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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,964

03/25/2004

Xiang-Jin Meng

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7042

7590

11/28/2006

Anne M. Rosenblum, Esq.  
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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/808,964

Applicant(s)

MENG ET AL.

Examiner

Stacy B. Chen

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 15, 16, 18-28 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 32 is/are allowed.
- 6) ☒ Claim(s) 15, 16, 18-22 and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/20/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's after-final amendment filed October 20, 2006 is acknowledged and entered. Claims 1-10, 15, 16, 18-28 and 32-38 are pending. Claims 23-28 remain withdrawn from consideration, being drawn to non-elected subject matter. Claims 1-10, 15, 16, 18-22 and 32-38 are under examination. Upon further consideration, new grounds of rejection are set forth in this non-final Office action. Finality of the previous Office action is withdrawn.

In a telephone conversation with Applicant's representative, Anne Rosenblum, on Friday, November 17, 2006, the examiner and attorney Rosenblum discussed possible claim amendments to place the instant application in condition for allowance.

#### ***Response to Amendment***

The rejection of claims 4-10, 15, 16 and 18-22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's amendment.

#### ***Claim Rejections - 35 USC § 112***

Claims 15, 16, 18-22 and 33-38 are rejected under 35 U.S.C. 112, first paragraph. The specification enables the inhibition of viral infection and prevention of PWMS with the PCV1-2 construct wherein the ORF2 capsid gene from PCV1 is replaced with the ORF2 capsid gene of the PCV2 (herein referred to as "the PCV1-2 capsid construct"). However, the specification does not reasonably provide enablement for protecting a pig against viral infection, which encompasses the prevention of even a single virion from infecting a single cell. Further, the

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specification does not reasonably provide enablement for preventing viral infection and PWMS with the PCV1-2 construct wherein any ORF from PCV1 is replaced with any ORF from PCV2.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims recite, “[A] viral vaccine that protects a pig against viral infection or postweaning multisystemic wasting syndrome”, and “[A] method of protecting a pig against viral infection or postweaning multisystemic wasting syndrome”, for example. Preventing even one virion from infecting a pig exposed to the virus is not possible. While the PCV ORF1-2 capsid construct is clearly capable of inhibiting PCV2 viral infection and preventing PMWS, there is no data in the specification that supports the prevention of a single virion from infecting an exposed pig. The general mechanism of the claimed vaccine is to induce an immune response that prevents the manifestation of PCV2 viral infection, PWMS. The immune system of the vaccinated pig is capable of inhibiting the progression of PCV2 viral infection so that PWMS is prevented.

With regard to the PCV1-2 capsid construct, the relevant non-patent literature and the specification demonstrates protective immunity against wild-type PCV2 infection (Fenaux *et al.*, *Journal of Virology*, 2004, 78(12):6279-6303). However, the swapping of any ORF other than ORF2 (capsid) has not been shown, nor has such a construct been indicated as protective against PCV2 infection. The specification does not disclose the construction of any other PCV1-2 chimeric virus (or DNA clone) or challenge experiments. Vaccination (prevention) efficacy requires challenge experiments in acceptable animal models. Applicant has demonstrated efficacy for one construct (PCV1-2 capsid), however, this single construct is not representative

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of all of the other PCV1-2 embodiments encompassed by claims 33, 34, 36 and 37. No other open reading frames have been indicated as suitable for swapping such that protective immunity is achieved. Given the breadth of the claims, the data provided in the specification, the state of the art, the lack of guidance relating to non-PCV1-2 capsid constructs, and lack of challenge experiments, the specification is not enabling for the full breadth of the claimed embodiments.

### ***Conclusion***

Claims 1-10 and 32 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Stacy B. Chen 11/27/06*  
STACY B. CHEN  
PRIMARY EXAMINER